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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,588	11/29/2001	Chen Xing Su	10209.353	6233
21999 7590 01/10/2008 KIRTON AND MCCONKIE 60 EAST SOUTH TEMPLE, SUITE 1800 SALT LAKE CITY, UT 84111				
			EXAMINER LEITH, PATRICIA A	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 01/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/997,588

Applicant(s)

SU ET AL.

Examiner

Patricia Leith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/19/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-28 is/are pending in the application.
- 4a) Of the above claim(s) 13-23,27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-12 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/07 has been entered.

Claims 1 and 5-28 are pending in the application.

Claims 13-23 and 27-28 were withdrawn on the merits as they are directed toward a non-elected invention.

Claims 1, 5-12 and 24-26 were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 103

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) and further in view of Gagnon (1997) in view of Elliot (US 1,885,401) for the reasons of record.

Claims 1, 4-12 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) in view of Gagnon (1997) in view of Brock et al. (1991) in view of Nahir (EP 0 555 573 A1) and in view of Elliot (US 1,885,401) for the reasons of record.

Response to Arguments

Applicant broadly argues that the cited references do not teach every aspect of the claimed invention (pp. 10-11, Remarks). Applicant specifically argues that "The method of making the product and the various constitutive elements added to the product before delivery have a significant effect on lipidperoxidation inhibition... the levels of lipidperoxidation inhibition experienced by utilizing the products and methods of the present invention are not merely intrinsic [*sic*] properties of Morinda citrifolia. The...in order to produce an improved Morinda citrifolia product, which has increased capacity to inhibit Lipidperoxidation " (p. 11, Remarks). However, to reiterate from the previous Office Action, this appears to be unsubstantiated allegation, as Applicant has

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not provided any convincing arguments nor evidence that would demonstrate that MCJ made by the claimed method would provide for 'increased capacity' of inhibiting lipidperoxidation. It remains deemed that the fruit juice as processed according to the claims is the same juice disclosed in the prior art, or so similar that no discernable differences could be made.

Applicant argues that an article submitted by Applicants, namely "Drug Development; The Pain Killer Tree: An Ancient Remedy Rediscovered" teaches that unexpected results are achieved when different processing steps are utilized (p. 11, Remarks). However, there is nowhere in the disclosure of this reference which indicates that the process *steps of the claimed invention* provides for any unexpected results. While Applicant again argues that 60/251,417 provides detailed studies showing an unexpected result (p. 11, Remarks), it is again reiterated that the data found in 60/251,417 does not substantiate the allegation that TNJ 'out performed' other MC juices/products, only that it has better oxygen scavenging capabilities than that of Vitamin C and grape extract.

Applicant argues that "Chye provides a non-enabling disclosure, which indicates that 'noni-juice is the new darling of health-conscious malaysians'....there have been no proper trials conducted with humans for verifying the efficacy of noni....various noni products are likely to hit the market which raises substantial questions...which form is

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best to take?...which juice is of the best quality...Which manufacturer guarantees quality control in the harvesting of the fruit and the bottling of the juice...Accordingly, Chye acknowledges that some noni products may be more effective than others and that some products may be dangerous to human health...Chye fails to provide guidance for overcoming this problem, Rather...After three years, during which time they were oblivious to Dr. Heinecke's own research on noni, they..developed a way to harvest, process and bottle the juice without sacrificing the important natural ingredients". Thus, Applicant indicates that Chye states that "...no assay had been performed with to verify efficacy of any noni product, and that nagging questions remained...only after three years of secret development did Steven Story and John Wadsorth develop a method, secret at the time, for preserving the ingredients....had developed a secret method for processing which allowed the bottling of the juice without sacrificing its important natural ingredients...Chye indicates that does not place into the public knowledge a process for processing the noni plant which preserves the natural efficacy of the plant during processing...Chye places the world in possession of the fact that a secret process exists, not in possession of the process for producing the product itself. Accordingly, Chye fails to teach or fairly suggest the process steps recited in the claims of the present invention" (pp. 12-13, Remarks).

According to Applicant's remarks, it appears that Applicant is stating that the Inventors performed the claimed invention with all of the method steps to prepare Tahitian Noni Juice ® as disclosed by Chye, but that the method for preparing TNJ was not known

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prior to this application; in Applicant's words, it was a 'secret method'. Applicant indicates that this process (as claimed, and according to Chye) preserved the active ingredients of TNJ. First, it is noted again, that Chye is not relied upon in a vacuum, this reference is combined with others in order to present the rejection under 35 USC 103(a). Chye did not teach the method for manufacture as Instantly claimed, hence the reasoning for combining Chye with the other references cited in the rejection. However, what Chye did teach, and what the reference is enabled for is that TNJ, comprising MC juice, grape juice and blueberry juice was known in the art and consumed at the time the Instant Invention was made. It is again reiterated that the data found in 60/251,417 does not substantiate the allegation that TNJ 'out performed' other MC juices/products, only that it has better oxygen scavenging capabilities than that of Vitamin C and grape extract.

Applicant argues that Schechter "does not describe a method of processing and administering the noni fruit so as to provide a stronger scavenging effect.." (p. 14, Remarks). Again, Applicant is arguing one reference, wherein the rejection as a whole is made over several references rendering the claims *prima facie* obvious.

While Applicant indicates that the method of the claimed invention provides for advantageous results with regard to preserving the natural ingredients of noni juice, it remains deemed that the process steps are made obvious by the combination of the prior art references. The steps in the method were known in the art prior to Applicant's

invention. These process steps for preparing juice were well known and documented in the art. There is nowhere in the Instant specification as filed which indicates that the MC juice manufactured by the steps claims *fairs any better than any known MC juice* with regard to biochemical processes such as oxygen scavenging. Applicant has not positively verified that manufacture of MC juice as set forth in the Instant claims preserves crucial active ingredients over MC juice which was known in the art. Therefore, lacking any evidence of unexpected results, it is deemed that the combination of the references makes obvious the claimed invention.

Applicant argues that "The Federal Circuit recently reaffirmed that in order for a reference to anticipate the claims...must provide a certain amount of disclosure..the disclosure in a assertively anticipating reference must be adequate to enable possession of the desired subject matter' Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research ..." Applicant further cites *In re Donohue*: "It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it...Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling... Thus in order for the cited art to anticipate or render obvious the Applicant's claims, it must put one skilled in the art in possession of all of the claim limitations" (p. 14). However, again, it appears that Applicant is not considering the claimed rejection as a whole under the statute of 35 USC 103(a). The cases cited by Applicants are particularly directed toward rejections

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under 35 USC 102(b) and not 35 USC 103(a). Nevertheless, it is deemed that the prior art as a whole did put the public in possession of the claimed embodiments in that all of the claimed embodiments were taught or suggested by the prior art cited of record in the outstanding rejections. Applicant has not specifically indicated any embodiment which is found in the claims which was not found in the prior art and merely alleges that the claimed invention is non-obvious over the combination of the prior art references.

Applicant again states that the references are not enabling: "Chye and Schechter both indicate that Tahitian Noni juice was ingested, but neither prior art reference disclosed the method for production...the references do not place one skilled in the art in possession of the products which are discussed, and do not place one of skilled in the art in possession of all of the claim limitations of the present invention " (pp. 14-15, Remarks). This argument is essentially rendered moot in light of the incorporation of Elliot into the rejection. However, it is noted that the references are enabled in that they disclosed Tahitian noni juice, which contained MCJ, blueberry and grape juice which was well known to be consumed. Lipid scavenging must have been an intrinsic consequence of the ingestion of this juice, and it must have scavenged lipids at the same intensity as that of the TNJ of the Instant specification in that they are deemed the same product. The particular manufacturing methods are deemed to be obvious in light of the combination of the references. Again, it is deemed that the manufacturing methods as claimed would have produced MCJ which would have been the same, or so similar to MCJ of the prior art that no discernable differences could be

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established. Applicant has not provided any evidence that the juice manufactured by the process as recited in the claims has any unexpected results over MCJ or TNJ of the prior art. It is further noted that while Applicant has clearly indicated that Elliot et al. are used in the rejection against the claims (see page 10, Remarks) Applicant has not specifically recognized the presence of Elliot et al. into the rejections or argued why this reference does not make obvious certain embodiments of the claimed invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

This is an RCE of applicant's earlier Application No. 09/997,588. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
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January 2, 2008

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a large, stylized loop at the end of the signature.